March 14, 2014

Supplemental Testimony of the American Chemistry Council's Opposition to
HB 5354
Committee on Children
Connecticut General Assembly

The American Chemistry Council is pleased to submit this supplemental testimony on HB 5354, as requested by the Committee on Children during its hearing on the bill on March 6, 2014. Specifically, the Committee requested information on existing chemicals in commerce subject to the Federal Toxic Substances Control Act (TSCA), 15 U.S.C.2601-2692.

Overview

Chemicals are developed, manufactured, distributed and used under a strict and comprehensive set of government rules found in more than a dozen separate federal laws. TSCA is the central law governing basic chemicals in commerce that have broad industrial, commercial and consumer uses.

Passed in 1976, TSCA gives the U.S. Environmental Protection Agency broad authority to require manufacturers to report information about the chemicals they make, to require manufacturers to screen and test their chemicals, and to regulate both new and existing chemicals. TSCA does not address chemicals that are pesticides, tobacco products, nuclear material or food, food additives, drugs, cosmetics or medical devices when manufactured for these purposes. These are addressed under other federal laws and regulations.

Under TSCA, EPA has the authority to limit or prohibit the manufacture and distribution of a chemical substance if it is found to pose an unreasonable risk. Under TSCA, chemical product makers are required to submit information on all newly developed chemicals to EPA. The agency evaluates this information before any new chemical can be used in commerce.

EPA maintains a TSCA inventory of both "new" and "existing" chemicals, allowing the agency to identify, evaluate and monitor any chemical that has ever been in U.S. commerce. If EPA has questions or concerns about the risks associated with a chemical, it may propose a rule requiring manufacturers to provide additional information or to perform testing. The laboratory practices for conducting chemical testing are also federally regulated. Toxicological test methods required by federal agencies are reviewed to assure that results are reproducible, accurate and meaningful.
In addition, TSCA has automatic reporting requirements under which chemical makers and importers must submit to EPA within 30 days *any* information (not already known to EPA) that reasonably supports the conclusion that a chemical poses a substantial risk of injury to human health or the environment.

Congress enacted TSCA in 1976 to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, and distribution in commerce, use, or disposal of chemical substances. TSCA seeks to accomplish its goals through a variety of regulatory mechanisms: the TSCA Inventory, new chemical review, significant new use rules (SNURs), consent orders, testing of existing chemicals, direct regulation of existing chemicals, reporting and recordkeeping requirements, import and export requirements, etc.

The initial Inventory contained approximately 62,000 chemical substances. The Inventory served to distinguish "existing chemicals" in commerce from "new chemicals" not on the Inventory that require advance notification to and review by EPA prior to manufacture for commercial purpose. EPA reviews the Premanufacture Notification (PMN) and evaluates the new chemical as a "gatekeeper" to assess potential risk or production/exposure concerns and based on this review

can impose conditions to restrict or ban manufacture, uses, releases, etc., and/or testing. Formal regulatory action is generally implemented through a Consent Order, which requires that EPA determine that the information available is insufficient to permit a reasoned evaluation of the chemical and that it "may present an unreasonable risk" or that it has substantial production and substantial/significant exposure/release. EPA has also relied on "voluntary" testing, including an informal "ban pending testing" arrangement to obtain testing that is relatively inexpensive to conduct (e.g., acute aquatic toxicity testing).

EPA can also impose SNURs on new chemicals that require advance notice to EPA prior to initiating the "significant new use." SNURs require consideration by EPA of a series of "factors" in taking the rulemaking and can be used to, in effect, extend the Consent Order requirements to other companies beyond the PMN submitter and/or more generally to require significant new use notification (SNUN) for uses beyond those identified in the PMN. SNURs are a very broad authority and are used frequently by EPA to control the uses, applications and potential applications of chemicals. Once a SNUN is filed with EPA, the agency gets another fresh look at the chemical as if the chemical was brand new to the marketplace and can require further testing if warranted before approving, refusing to approve the new use, or something in between such as attach a Consent Order and control its uses and applications further while the chemical is in commerce.

The "existing chemicals" were grandfathered under TSCA without any requirement for EPA review, but TSCA section 8(e) did mandate immediate reporting of "substantial risk" information to EPA by manufacturers, processors, and distributors and EPA also received broad authority to require by rule, among other things, reporting of existing exposure and hazard information, to require testing and to regulate unreasonable risks.

Chemicals that are listed on the Inventory are never removed from the Inventory, but that does not mean that they are active in commerce. EPA requires manufacturers and importers to update the agency every four years on the number of chemicals they manufacture and import at or above a particular threshold (currently set at 25,000 pounds per facility site per year). The 2012 CDR reports 7,800 non-confidential chemicals in commerce at the reporting threshold. Almost certainly there are actually more than 7,800 in commerce, accounting for various substances exempt from CDR reporting such as non-PMN submissions (Low Volume Exemptions, Low Release/Low Exposure Exemptions, Test Market Exemptions, certain low hazard polymers) and exempt uses not subject to submission (R&D) are not listed on the TSCA Inventory, but there are not 84,000 currently in commerce. We anticipate that a modernized TSCA will address this issue by requiring an Inventory clarification of active versus inactive chemicals in commerce, but until that time, or some action by EPA under current TSCA to distinguish between them, we cannot know for certain the precise number.

Since the TSCA Inventory was established in 1979, EPA has reviewed more than 36,000 new chemical submissions (PMNs) and an additional 13,000 PMN exemption notices. Below is a breakdown of the submissions and notices.

New Chemicals Program 1979 Through September 30, 2010

Type of Submission	Number Submitted Since 1979
Premanufacturing Notices	36,623
Test Marketing Exemption Applications (TMEA)	796
Low Volume Exemptions (LVE)	10,423
Low Release/Low Exposure Exemptions (LoRex)	77
Polymer Exemptions*	2,530
Total**	50,449

Regulatory Action on PMNs	Number Issued

5(e) consent orders	1,492
Followed by 5(e) SNURs	(757)
Non-5(e) SNURs	797
PMNs withdrawn in face of action	1,848
Voluntary testing actions	300^{+}
Total cases regulated	4,441

EPA has issued more than 300 SNURs on existing chemicals, including a number of PBTs (e.g., 6 PBBs (polybrominated biphenyls, the brominated analogue of PCBs, 2 PBDEs (polybrominated diphenyl ethers), and over 270 PFAS (perfluoroalkyl sulfonate derivatives), known or suspected carcinogens (including 24 benzidine dyes, the flame retardant "tris", and erionite (an asbestos-like fiber)), and others.

Another way the agency regulates existing chemicals in commerce is through the use of voluntary initiatives, such as the 2010/2015 PFOA Stewardship Program, in which 8 companies committed to reduce their global facility emissions and product content of PFOA and related long-chain perfluorinated chemicals (PFCs) by 95% by 2010, and to work toward eliminating all emissions and product content by 2015.

Creating the TSCA Inventory in the late 1970s was unprecedented at the time. No government had ever before tried to compile an authoritative list of the chemicals in commerce and EPA's completion of it with three years of TSCA's enactment was no mean feat. The TSCA Inventory served as the standard and model for other national inventories developed since then, and many of the policies, approaches, and terminology developed in the initial TSCA Inventory have been utilized by other countries.

Conclusion

ACC hopes this information is helpful to the Committee's understanding of the current work and review of TSCA, which effectively evaluates substances before they are permitted to enter the marketplace.